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PATENT  
Attorney Docket No. 056291-5174-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: <b>GELLERT <i>et al.</i></b>	)	Confirmation No. <b>3886</b>
	)	
Application No.: <b>10/505,231</b> ✓	)	Group Art Unit: <b>1615</b>
	)	
Filed: <b>August 19, 2004</b>	)	Examiner: <i>Unassigned</i>
	)	
For: <b>PHARMACEUTICAL FORMULATION OF</b>	)	
<b>IRESSA COMPRISING A WATER-SOLUBLE</b>	)	
<b>CELLULOSE DERIVATIVE</b>	)	Date: <b>August 4, 2006</b>

Commissioner for Patents  
U.S. Patent and Trademark Office  
Customer Window, **Mail Stop Amendment**  
Randolph Building  
401 Dulany Street  
Alexandria, VA 22314

Sir:

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

**UNDER 37 C.F.R. § 1.97(b)**

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants petition the Examiner to consider this Supplemental Information Disclosure Statement and documents listed on the attached Form PTO-1449. To the best of the undersigned's knowledge, this Supplemental Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits for the above-referenced Application. Accordingly, Applicants do not believe a fee is due for filing this Supplemental Information Disclosure Statement.

With the exception of U.S. Patents and Publications, copies of the listed documents are attached. Applicants respectfully request that the Examiner initial and return the Form PTO-1449, indicating that the information has been considered and made of record herein.

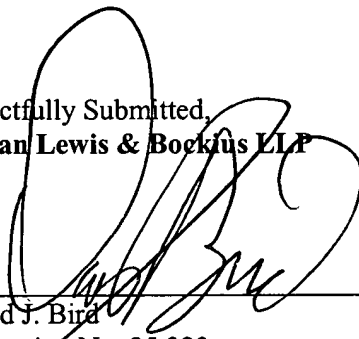
This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If it should be determined that the listed documents constitute "prior art" under United States law,

Applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such document.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

**Except** for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. §1.136(a)(3).

Respectfully Submitted,  
**Morgan Lewis & Bockius LLP**



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<b>INFORMATION DISCLOSURE CITATION</b> (Use several sheets if necessary)				Attorney Docket No. 056291-5174-US		Application No. 10/505,231	
PTO Form 1449 August 4, 2006				Applicants: <b>GELLERT et al.</b>			
Filing Date: August 19, 2004				Group Art Unit: 1615			

**U.S. PATENT DOCUMENTS**

Initial	Document No.	Date	Name	Class	Sub-Class	Filing Date
	1. 20050209229	September 22, 2005	Gilday et al.	514	234.2	May 23, 2005
	2. 20020177601	November 28, 2002	Himmelsbach et al.	514	266.2	August 23, 2001
	3. 5,610,193	March 11, 1997	Al-Razzak et al.	514	616	May 22, 1996
	4. 4,178,376	December 11, 1979	Higuchi et al.	514	311	January 21, 1977
	5. 3,608,063	September 21, 1971	Banker	424	485	August 15, 1969

**FOREIGN PATENT DOCUMENTS**

	Document No.	Date	Country	Class	Sub-Class	Translation
	6. DE 3233764	May 7, 1987	Germany			Yes
	7. EP 1027888	August 16, 2000	EPA			
	8. EP 103387	March 21, 1984	EPA			
	9. EP 640341	March 1, 1995	EPA			
	10. GB 1278816	June 21, 1972	Great Britain			
	11. JP 05-255066	October 5, 1993	Japan			Yes
	12. JP 62-123117	June 4, 1987	Japan			Yes
	13. WO 95/09614	April 13, 1995	WIPO			
	14. WO 97/02017	January 23, 1997	WIPO			
	15. WO 98/55148	December 10, 1998	WIPO			
	16. WO 00/16776	March 30, 2000	WIPO			Yes
	17. WO 00/55141	September 21, 2000	WIPO			
	18. WO 00/56338	September 28, 2000	WIPO			
	19. WO 02/06834	January 24, 2002	WIPO			
	20. WO 02/64132	August 22, 2002	WIPO			
	21. WO 02/65834	August 29, 2002	WIPO			
	22. WO 03/017940	March 6, 2003	WIPO			
	23. WO 03/024426	March 27, 2003	WIPO			
	24. WO 03/024429	March 27, 2003	WIPO			
	25. WO 03/024430	March 27, 2003	WIPO			
	26. WO 03/072139	September 4, 2003	WIPO			

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)**

27.	Baselga et al. "Phase I safety, pharmacokinetic, and pharmacodynamic trial of ZD1839, a selective oral epidermal growth factor receptor tyrosine kinase inhibitor, in patients with five selected solid tumor types" J Clin Oncol. 20(21): 4292-4302 (2002)
28.	Berger et al. "Supersaturation of sulfates in electrodialysis" Ind. Eng. Chem., Process Design Develop. 1: 229-236 (1962) Abstract
29.	Brewster et al. "A Novel Cyclodextrin-containing Glass Thermoplastic System (GTS) for Formulating Poorly Water Soluble Drug Candidates: Preclinical and Clinical Results" Journal of Inclusion Phenomena and Macrocyclic Chemistry 44(1-4): 35-38 (2002)

Examiner	Date Considered
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**Examiner:** Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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<b>U.S. PATENT DOCUMENTS</b>							
Initial		Document No.	Date	Name	Class	Sub-Class	Filing Date
<b>FOREIGN PATENT DOCUMENTS</b>							
		Document No.	Date	Country	Class	Sub-Class	Translation
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)</b>							
	30.	Capello et al. "Percutaneous penetration of Ibuprofen from supersaturated solutions" Acta Technologiae et Legis Medicamenti XIII(1): 25-35 (2002) (Translation enclosed)					
	31.	Espinoza "Influence of admixed citric acid on the release profile of pelanserin hydrochloride from HPMC matrix tablets" Int J Pharm. 201(2):165-173 (2000)					
	32.	McKillop et al. "Cytochrome P450-dependent metabolism of gefitinib" Xenobiotica 35(1): 39-50 (2005)					
	33.	McKillop et al. "Metabolic disposition of gefitinib, an epidermal growth factor receptor tyrosine kinase inhibitor, in rat, dog and man" Xenobiotica 34(10): 917-934 (2004)					
	34.	Munday "Film coated pellets containing verapamil hydrochloride: enhanced dissolution into neutral medium" Drug Development and Industrial Pharmacy 29(5): 575-583 (2003)					
	35.	N Magné et al. "Sequence-dependent effects of ZD1839 ('Iressa') in combination with cytotoxic treatment in human head and neck cancer" British Journal of Cancer 86: 819-827 (2002)					
	36.	Nakagawa et al. "Phase I pharmacokinetic trial of the selective oral epidermal growth factor receptor tyrosine kinase inhibitor gefitinib ('Iressa', ZD1839) in Japanese patients with solid malignant tumors" Ann Oncol. 14(6): 922-930 (2003)					
	37.	Neiman et al. "Separation of a highly dispersed fraction in supersaturated solutions during formation of calcium sulfate precipitates" Kolloid. Zh. 35(4): 781-783 (1973) Abstract					
	38.	Venkatesh "Development of controlled-release SK&F 82526-J buffer bead formulations with tartaric acid as the buffer" Pharm Dev Technol. 3(4):477-485 (1998)					
Examiner				Date Considered			
<b>Examiner:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							